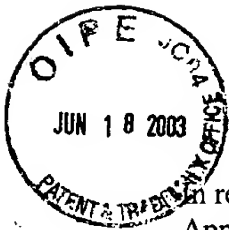


Attorney's ~~Handwritten~~ 038151/195944

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Hanley et al.  
Appl. No.: 09/560,288  
Filed: April 27, 2000  
For: METHOD FOR PRODUCING HUMAN  
INTERVERTEBRAL DISC CELLS

Confirmation No.: 3083  
Group Art Unit: 1647  
Examiner: Robert C. Hayes

#19  
B.G.  
7/9/03

June 16, 2003

Commissioner for Patents  
Post Office Box 1450  
Alexandria, VA 22313-1450

DECLARATION PURSUANT TO  
37 C.F.R. § 1.132

We, Dr. Helen E. Gruber and Dr. Edward Nathaniel Hanley, Jr., declare and state:

1. That we are the Dr. Helen E. Gruber and Dr. Edward Nathaniel Hanley, Jr. named as the inventors of United States Patent Application No. 09/560,288, filed April 27, 2000 entitled "Method of Producing Human Intervertebral Disc Cells, said application being a continuation-in-part of United States Patent No. 6,080,579, having a filing date of November 26, 1997.
2. We understand that the U.S. Patent Office has rejected the claims of our above-identified patent application over an article entitled "Human Intervertebral Disc Cells from the Annulus: Three-Dimensional Culture in Agrose or Alginate and Responsiveness to TGF- $\beta$ 1", Experimental Cell Research 235, 13-21 (1997) ("Experimental Cell Paper") and an article "Characterization and Phenotype Stability of Human Disc Cells *In Vitro*", Matrix Biology, Vol. 16/1997, pages 281-284 ("Matrix Paper") that were cited by the Examiner to reject the claims under 35 U.S.C. § 102(a).
3. We are the Dr. Helen E. Gruber and Dr. Edward Nathaniel Hanley, Jr. who along with E. Carl Fisher, Jr., Bhaloo Desai, Audrey A. Stasky and Gretchen Hoelscher are

named as coauthors on the Experiment Cell Paper and as coauthors along with Audrey A. Stasky on the Matrix Biology Paper.

4. The invention described and claimed in the application was conceived solely by us.
5. E. Carl Fisher, Jr., Bhaloo Desai, Audrey A. Stasky and Gretchen Hoelscher worked in the laboratory at Carolinas Medical Center where Dr. Gruber, at the time, held an appointment as Senior Scientist and Director of Research Histology, Orthopedic Research Biology and Dr. Hanley was on staff.
6. The experiment that were conducted were discussed with E. Carl Fisher, Jr., Bhaloo Desai, Audrey A. Stasky and Gretchen Hoelscher after Dr. Hanley and Dr. Gruber together conceived of the invention. The coauthors, along with Dr. Gruber and Dr. Hanley, carried out these experiments in the laboratories at Carolinas Medical Center under the inventors' supervision.
7. These experiments demonstrated for the first time that intervertebral disc cells could be cultured and made into a three-dimensional structure and implanted into a target disc area.
8. The naming of E. Carl Fisher, Jr., Bhaloo Desai, Audrey A. Stasky and Gretchen Hoelscher as coauthors on the cited papers in no way relates to their being a coinventor of the invention. It is our practice to name as coauthors on manuscripts concerning research carried out in our laboratory coworkers, including technicians, who contribute to the research without regard to considerations concerning inventorship. It is for this reason that E. Carl Fisher, Jr., Bhaloo Desai, Audrey A. Stasky and Gretchen Hoelscher were named as coauthors.
9. In summary, we alone conceived the invention described and claimed in the subject application and the invention was thereafter actually reduced to practice on several occasions including experiments carried out by E. Carl Fisher, Jr., Bhaloo Desai, Audrey A. Stasky and Gretchen Hoelscher, technicians working in our laboratory under our direction and supervision.

In re: Hanley et al.  
Appl. No.: 09/560,288  
Filed: April 27, 2000  
Page 3

We hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statement may jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor Edward Nathaniel Hanley, Jr.  
Inventor's signature *Edward Nathaniel Hanley, Jr.*  
Date 06/16/03 Country of Citizenship U.S.  
Residence Charlotte, North Carolina  
Post Office Address 2210 Sutton Springs Road  
Charlotte, North Carolina 28226

Full name of second inventor Helen Elizabeth Gruber  
Inventor's signature *Helen E Gruber*  
Date 06/16/03 Country of Citizenship U.S.  
Residence Charlotte, North Carolina  
Post Office Address 3820 Windwood Circle  
Charlotte, North Carolina 28226